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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,436	02/14/2001	Corine A. M. Vernet	15966-672	1641

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/10/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/783,436	VERNET ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,29,32 and 49-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,29,32 and 52-54 is/are allowed.
- 6) ☒ Claim(s) 49-51 and 55-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 12, mailed on January 24, 2003), Applicants filed an amendment and response received on April 24, 2003 (Paper No. 13). Said amendment cancelled Claims 2-4 and 44-48, amended Claims 1, 29, and 32, and added new Claims 49-57. Thus, Claims 1, 29, 32, and 49-57 are pending in the instant Office action and will be examined herein.

Priority

2. As previously noted the instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/182,637 filed on February 15, 2000, 60/237,862 filed on October 4, 2000, and 60/240,316 filed on October 13, 2000.

Withdrawn - Objections to the Specification

3. All objections to the SEQ ID numbering in the Tables are withdrawn with respect to the NOV sequences (except with respect to Table 18 and NOV5) disclosed by virtue of Applicant's amendment. However, no changes to the other sequences noted have been made. Those objections are maintained below.

4. Previous objection to Table 5 is withdrawn by virtue of Applicant's amendment; the previous description of NOV1 appears to be a typographical error. The correct description is of NOV2 as amended by Applicants.

Art Unit: 1652

5. Previous objection to the description of NOV3 on page 10, because the NOV3 polypeptide is described as SEQ ID NO: 6, a 617 amino acid polypeptide; however, SEQ ID NO:6 is a 616 amino acid polypeptide in the sequence listing, is withdrawn by virtue of Applicants' amendment changing SEQ ID NO:6 in the sequence listing to a 617 amino acid protein. Without explanation or support for this amendment, a new matter objection is set forth below.
6. Previous objection to the specification for the abbreviation "NOVX" not being defined is withdrawn by virtue of Applicants' amendment.
7. Previous objection to the specification for a typographical error on page 30, line 21, in the description of NOV7, is withdrawn by virtue of Applicant's amendment.
8. Previous objection to the numbering of NOV7 in Table 25 on pages 33-34 is withdrawn by virtue of Applicants' amendment.
9. Previous objection to the specification for being confusing concerning the functions of NOV7 and NOV3 is withdrawn by virtue of Applicants' amendment to Table 1 in the specification to recite a probable function for NOV3 noted elsewhere in the text of the specification.
10. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicants' amendment to the title.

New or Maintained – Objections to the Specification

11. Previous objection to the Tables where they contain different SEQ ID NOs identifying identically labeled sequences is maintained. Applicants argue that these are different sections from the same sequence. However, for the Tables to be clear, the descriptors, such as “CHR Y,” should be written as ---CHR Y **fragment**--- or similar language so that the sequences (with different SEQ ID NOs) in the Tables need not be the same as indicated by having the same label.

This confusion is found in the following Tables:

- a) Tables 7 and 8 both recite CHR Y nucleic acid sequences, but with different SEQ ID NOs to reference them.
- b) Tables 9, 11, and 25 all recite GLY T polypeptide sequences, but with different SEQ ID NOs to reference them.
- c) Table 15 recites two different PP1201 nucleic acid sequences, but with different SEQ ID NOs to reference them.
- d) Tables 16 and 20 both recite CHR 2 nucleic acid sequences, but with different SEQ ID NOs to reference them.

Appropriate correction is required.

12. Previous objection to Table 18 on page 24 is maintained. Applicants did not address this issue. NOV5 polypeptide is labeled as SEQ ID NO:38 in Table 18 while the text describes NOV5 polypeptide sequence as SEQ ID NO:10. Which description is correct? Clarification is required.

13. Previous objection to the specification for having inappropriate Tables 2-27 imbedded in the text is maintained. Applicants argue that “the specification ... may contain chemical and mathematical formulas, but shall not contain drawings or flow diagrams. The description portion of the specification may contain tables.” The Examiner maintains that the sequence alignments

Art Unit: 1652

proposed in Tables 2-27 are **neither** chemical **nor** mathematical formulae. Moreover, they **cannot** be described as tables since no columns or rows are found, and particularly no experimental data is displayed. The information in these portions of the specification labeled “Tables” 2-27 must be removed and entered into the specification as new drawings whose descriptions are found in the specification under “Brief Descriptions of the Drawings”.

Correction is required.

14. Previous objection to the Abstract for not completely describing the disclosed subject matter is maintained. The Abstract, as amended by Applicants on April 24, 2003, describes the claimed invention only. As noted in M.P.E.P. § 608.01(b), the Abstract must describe the disclosed subject matter in its entirety, not just the claims. Correction is required.

15. The amendment filed April 24, 2003 to the sequence listing (Paper No. 13) is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

a) SEQ ID NO:6 in the sequence listing was originally filed as a 616 amino acid protein. As amended on April 24, 2003 in the Sequence Listing, SEQ ID NO:6 is now a 617 amino acid protein. Applicants have added an “Xaa” at position 50 of SEQ ID NO:6, with respect to the sequence as originally filed, to alter the length of the protein. It is unclear where support can be found for the change in the application as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Withdrawn - Claim Objections

16. Previous objection to Claims 1-4, 29, and 32 for a typographical error is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

17. Previous rejection of Claims 1-4, 29, and 32 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "mature form" is withdrawn by virtue of Applicants' amendment removing said term.

18. Previous rejection of Claim 4 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "conservative" substitution is withdrawn by virtue of Applicants' cancellation of said claim.

19. Previous rejection of Claims 1, 4, 29, and 32 under 35 U.S.C. § 112, first paragraph, written description, for claiming products with some structural but no functional limitation is withdrawn by virtue of Applicants' amendment. Claim 1 requires a specific structure and new claims 49 and 52 contain a large enough portion of the disclosed full-length polypeptide that its inherent activity cannot be reasonably questioned. However, this is not the case for Claims 55-57 – see rejection below.

20. Previous rejection of Claims 2 and 3 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of said claims.

New or Maintained - Claim Rejections - 35 U.S.C. § 112

21. Claims 55-57 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 55 is drawn to polypeptide sequences that comprise a portion of SEQ ID NO:14 without also limiting the function of the claimed polypeptides.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation.

The instant specification discloses an N-acetylglucosaminyl transferase and fragments thereof. Applicants have fully described the genus relating to said SEQ ID NO with both sequence fragment limitations and functional limitations (i.e., having N-acetylglucosaminyl transferase function). However, the genus of the instant claims also contains polypeptides within

Art Unit: 1652

the sequence fragment limitations, but having different function. Applicants have not fully described a genus that has sequence fragment limitations in the absence of functional limitations.

22. Claims 49-51 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The fragment of 67-695 of SEQ ID NO:14 is not described in the specification as originally filed. A notation of the related DNA fragment is described, but not the polypeptide encoding it. Thus, a claim to a polypeptide encodes by the described DNA fragment would not be considered new matter. Correction is required.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

23. Previous rejection of Claims 1, 29, and 32 under 35 U.S.C. § 102(b) as being anticipated by WO9846757 is withdrawn by virtue of Applicant's amendment. The fragments in the new claims are not anticipated by the instant art.

Withdrawn - Claim Rejections - 35 U.S.C. § 103

24. Previous rejection of Claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession Number AW177837 in view of Bork *et al.* is withdrawn by virtue of Applicants' amendment limiting the claims to exact protein sequences not taught by GenBank.

Art Unit: 1652

Other Art of Interest

25. Previously cited WO 02/26950 (Lal *et al.*) discloses SEQ ID NO:14 that is 93% identical to Applicants' SEQ ID NO:14 (see attached alignment). The sequence of Lal *et al.* contains the 158-338 fragment in Claim 55.

Summary of Pending Issues

26. The following is a summary of the issues pending in the instant application:
- a) The specification stands objected to for the Tables where they contain different SEQ ID NOs identifying identically labeled sequences.
 - b) The specification stands objected to for Table 18 where the NOV5 polypeptide is identified by SEQ ID NO:38 where elsewhere in the specification it is SEQ ID NO:10.
 - c) The specification stands objected to for containing inappropriately imbedded figures in the text.
 - d) The Abstract stand objected to.
 - e) The amendment to the sequence listing filed April 24, 2003 stands objected to for adding new matter into the specification.
 - f) Claims 55-57 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
 - g) Claims 49-51 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.

Allowable Subject Matter

27. The closest prior art to SEQ ID NO:14 and particular fragments thereof was previously noted as GenBank Accession Number AW177837 teaches a 675 bp mRNA whose sequence exactly encodes SEQ ID NO: 14 residues 176-400 (of the full-length 695 sequence). GenBank Accession Number AW177837 does not teach the encoded protein of the EST. Nor does GenBank Accession Number AW177837 teach methods of identifying a full-length gene and producing its protein product. Since the allowable claims are drawn to exact sequence, anything short of full disclosure of the exact sequence renders the claims unpredictable in this case.

Conclusion

28. Claims 1, 29, 32, and 52-54 are allowed. Claims 49-51 and 55-57 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



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KMK
July 5, 2003